

**REMARKS**

Claims 41-46, 48, 51-55, 71-76 and 79-84 are pending and under consideration. The independent claims have been amended to specify that in methods of active immunotherapy, the agent is either linked to a carrier or administered with an adjuvant. Support is provided by e.g., paragraphs 95 and 48 of the specification respectively.

**Rejections under 35 USC 112, first paragraph**

Claims 41-46, 48 and 50-55 are still rejected on the basis that the definition of "therapeutically treating" provided in the specification includes patients suspected of having Parkinson's disease implying that the claims to therapeutically treating encompass prophylactic treatment and thus absolute prevention of the disease. In reply, irrespective that the specification may provide a broader definition of therapeutically treating, claims 41 and 44 recite that the patient is suffering from Parkinson's disease. Thus, the claims do not encompass complete prevention of the disease in patients not having the disease. Accordingly, it is respectfully submitted that the rejection should be withdrawn against these claims.

With respect to claims 71-76 and 78-80, which are directed to prophylactic treatment, the office action incorrectly states that claims are directed to treating persons with no signs, symptoms or risks for Parkinson's disease. To the contrary, the claims specify that the patient has a known genetic risk of Parkinson's disease. Therefore, most of the office action's comments directed to alleged difficulties of prophylaxis of patients not having a known genetic risk of Parkinson's disease are not relevant to the claims now pending.

The office action also intimates that the efficacy to side effects ratio is less favorable for prophylaxis than treatment (office action at pp. 11-13.) Even if this is true, it is submitted to be an issue for the patient, the treating physician and the FDA rather than the Patent Office. Few approved drugs, particularly those for treating serious diseases, are entirely free of side effects. The requirements under the law for obtaining a patent are not as stringent as the requirements for obtaining government approval to market a particular drug for human consumption. *In re Brana*, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995).

In any event, the results of Su are not predictive of the extent of side therapeutics in a method of treatment. The purpose of Su's study was to assess toxic effects of A $\beta$  rather than to assess treatment. Consequently, Su administered A $\beta$  at a much higher frequency that would be necessary or desirable in a method of immunotherapy. Specifically, Su administered A $\beta$  twice a day every day. By contrast typically frequencies of administration in the presently claimed methods are at intervals of weeks or months (see specification at p. 139). Thus, Su's study represents a regime of extreme high exposure specifically designed to promote toxic effects. Such a regime could easily avoided in a therapeutic method and is not detrimental to enablement.

As to Schenk's report of side effects in 5% of patients, it is respectfully submitted that such a level of side effects is not inconsistent with enablement under *In re Brana*. Moreover, these side effects were experienced from administering full-length A $\beta$  peptide and would likely be avoided by administering fragments or passive administration of antibodies, as discussed by Schenk (see p. 828, first column, last paragraph).

With respect to Hooper's discussion of a possible neurological role of APP, it is noted that administration of A $\beta$  for about seven months in a transgenic mouse model of Alzheimer's disease had no effect on APP levels (see WO00/72880, Example III, particularly p. 59, first paragraph). Thus, the allegation that prophylactic treatment as claimed would cause insurmountable side effects through depletion of APP is merely speculation.

For these reasons, it is respectfully submitted that the rejection should be withdrawn.

#### **Rejections under 35 USC 102(a) and 103**

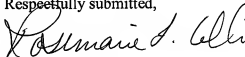
The Examiner does not expand on previous rejections, which have already been addressed in the appeal brief. Therefore, applicant has no additional comments at this time.

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PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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